IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

PERNIX IRELAND PAIN DAC and PERNIX THERAPEUTICS, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. 16-139-WCB
ALVOGEN MALTA OPERATIONS LTD.,	)	
Defendant.	)	

ALVOGEN'S REPLY BRIEF IN SUPPORT OF ITS MOTION TO STRIKE AND EXCLUDE PERNIX'S LATE-DISCLOSED INFRINGEMENT THEORY

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If Pernix had timely disclosed its single-actor infringement theory, it would not have needed 11 pages of briefing to respond to a 5-page motion—it could have simply identified where the theory appears in its expert reports and contentions. Yet Pernix does not even address—let alone dispute—the fact that its expert did not disclose a single-actor infringement theory in his report. Instead, Pernix argues that it presented its single-actor infringement theory in its original contentions, claiming that it only added joint infringement as an alternative. But Pernix *never* disclosed the theory it now presents on summary judgment—i.e., that all of the claimed steps are performed by a patient.

Pernix also argues that it made Alvogen aware of its intent to pursue a single-actor infringement theory through *Pernix's* deposition of *Alvogen's* non-infringement expert. Pernix then claims that Alvogen could have cured any prejudice by asking Pernix's expert about its single-actor infringement theory at his deposition—despite that theory appearing nowhere in his report. Pernix's arguments only serve to highlight the prejudice to Alvogen from being forced to respond to this new theory just two months before trial.

I. The Parties Agree on the Applicable Legal Standards

Pernix begins its brief with an attempt to obfuscate the relevant legal standards, suggesting that Alvogen should have filed its motion under Rule 37(c)(1) rather than Rule 37(b)(2). But regardless of whether the Court finds that Pernix's late disclosure violated the deadlines for fact and expert discovery provided by the scheduling order (Rule 37(b)(2)) or its duty to supplement (Rule 37(c)(1)), the parties agree that the Court should apply the Pennypack

factors to determine whether exclusion is warranted under Rule 37.[1] Pernix's quarreling over which subsection of the rule it violated is nothing more than a distraction.

II. Pernix Cannot Seriously Dispute That It Failed to Disclose a Single-Actor Infringement Theory in Its Amended Contentions and Expert Reports

Pernix contends that it did not shift from a single-actor infringement theory to a joint infringement theory because "Pernix only ***added*** language in its amended infringement contentions[.]" D.I. 148 at 1 (emphasis in original).[2] While Pernix did not remove words from its original contentions when it amended them, the words it added changed the meaning of the contentions to specify two actors. As shown in the chart below, Pernix's original contentions made clear that a physician must perform at least one step of the claimed method (and, therefore, the claims could not be infringed by a patient alone). After Pernix submitted those contentions, the Court construed the claim to require that the "administering" step be carried out by a patient. Pernix does not dispute that its amended contentions, served after the Court issued its claim construction order do not disclose the theory it advances on summary judgment—that the patient is a single actor. Rather, they state that the patient carries out the "administering" step as construed by the Court, while the physician continues to carry out other steps of the claimed methods:

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[1] Pernix contends that "Alvogen's Motion should be denied because it fails to address the Tritek factors." D.I. 148 at 2. As Pernix's cited case makes clear, those factors assist the court "in determining whether a party has breached its duty to amend a discovery response"—not in determining whether exclusion is warranted where a party asserts a belated infringement theory. Boehringer Ingelheim Int'l GmbH v. Barr Labs. Inc., C.A. No. 05-700-JJF, 2008 U.S. Dist. LEXIS 53475, at *4 (D. Del. July 15, 2008). Pernix's brief makes no further mention of Tritek, and it appears to agree that the Court should apply the Pennypack analysis.

[2] Pernix also briefly suggests that it timely disclosed its single-actor infringement theory because it "raised this theory in its Complaint[.]" D.I. 148 at 4. Broad infringement allegations in a complaint are no substitute for timely disclosure of a plaintiff's actual infringement contentions, and Pernix cannot seriously contend otherwise.

Claim Term	Original Contentions	Amended Contentions
administering to the patient having mild or moderate hepatic impairment a starting dose	ALVHYDRO-PTX00000284-87; ALVHYDRO-PTX00000295; ALVHYDRO-PTX00000306-07 Alvogen's Draft Label provides instructions for administering a starting dose of its proposed generic product to patients having mild or moderate hepatic impairment.	ALVHYDRO-PTX00000284-87; ALVHYDRO-PTX00000292-95; ALVHYDRO-PTX00000306-07 Alvogen's Draft Label provides instructions for administering a starting dose of its proposed generic product to patients having mild or moderate hepatic impairment. Physicians direct and/or control their patients' administration of a starting dose of Alvogen's proposed generic product in such a manner as to condition the receipt of treatment on the patients' administration of the prescribed starting dose. Further, the physician establishes the manner and timing of the patients' administration of the starting dose.
wherein the starting dose is not adjusted relative to a patient without hepatic impairment.	ALVHYDRO-PTX00000287; ALVHYDRO-PTX00000295; ALVHYDRO-PTX00000306-07 Alvogen's Draft Label ***instructs physicians*** that the starting dose of Alvogen's proposed generic product is not adjusted for patients with mild or moderate hepatic impairment relative to a patient without hepatic impairment.	ALVHYDRO-PTX00000287; ALVHYDRO-PTX00000292-95; ALVHYDRO-PTX00000306-07 Alvogen's Draft Label ***instructs physicians*** that the starting dose of Alvogen's proposed generic product is not adjusted for patients with mild or moderate hepatic impairment relative to a patient without hepatic impairment. Physicians direct and/or control their patients' administration of a starting dose of Alvogen's proposed generic product in such a manner as to condition the receipt of treatment on the patients' administration of the prescribed starting dose. Further, the physician establishes the manner and timing of the patients' administration of the starting dose.

D.I. 125, Ex. A and B (emphasis added).

If Pernix's amended contentions left any doubts about whether it was asserting a patient-as-single-actor infringement theory, those doubts were dispelled when its infringement expert, Dr. Gudin, only presented a joint infringement theory in his expert report (a fact that Pernix neither addresses nor disputes). Although Pernix again tries to paint this as "Alvogen's joint infringement defense[,]" it ignores Dr. Gudin's actual affirmative infringement opinion:

> As explained below, all of the elements of claim 1 of the '760 Patent are met by Alvogen's Proposed ANDA Product because ***a physician***, as instructed by the Alvogen Draft Label, ***will direct a patient*** with mild or moderate hepatic impairment to take the same starting dose of Alvogen's Proposed ANDA Product as a patient without hepatic impairment (*i.e.*, "the starting dose is not adjusted relative to a patient without hepatic impairment"), ***and the dosage form will be self-administered by the patient as directed by the physician***.

D.I. 125, Ex. 4 at ¶ 69 (emphasis added); id. at ¶ 73 ("the physician and patient jointly practice the claimed method"), ¶ 74 ("The patient's receipt of the prescribed dose of drug (through filling the doctor's prescription) is conditioned upon the understanding that the patient will use the drug exactly as prescribed, and it is the physician who dictates the manner and timing of the patient's self-administration of the drug."), ¶ 80 ("physicians will thus direct patients to mild or moderate hepatic impairment to take the same starting dose taken by patients without hepatic impairment"). The suggestion that Dr. Gudin was simply responding to "Alvogen's joint infringement defense" does not hold water.

III. Pernix's Prejudice Arguments and Alvogen's Deposition Objections Highlight the Serious Harm Caused by Pernix's Sandbagging

Pernix's arguments on prejudice illustrate the harm caused by its late disclosure. First, Pernix argues that Alvogen's non-infringement expert would not have attempted to rebut Pernix's single-actor infringement theory "because there are no issues of fact relating to the single-actor theory." D.I. 148 at 6-7. Pernix cites no authority that an infringement theory may

be omitted from an expert report if the plaintiff believes that there are no underlying factual issues.

Moreover, as shown by Pernix's improper questioning of Alvogen's expert, Dr. Candiotti, there are serious factual flaws with Pernix's single-actor infringement theory that he would have addressed in his rebuttal report—including, for example, that the patient does not prescribe or set a dose amount. Dr. Candiotti also would have addressed whether Alvogen's label encourages a patient to carry out the steps of the claimed methods. For this reason (and those set forth in Alvogen's summary judgment opposition), Pernix is also wrong that "Alvogen and its expert ***do not dispute*** patients will infringe claims 1-4 and 11[.]" D.I. 148 at 7 (emphasis in original).

Second, Pernix argues that Alvogen should have been on notice of its single-actor infringement theory because Pernix asked Alvogen's expert a series of hypothetical questions about single-actor infringement at his deposition. Alvogen's objections to this unfair line of questioning show the serious harm in surprising a witness with questions about a new infringement theory that was never disclosed in Pernix's contentions or discussed in any expert report. Improper sandbagging of an expert does not constitute fair notice of an infringement theory that was never part of Pernix's infringement case.

Third, Pernix argues that Alvogen could have cured any prejudice by asking Pernix's expert, Dr. Gudin, about single-actor infringement at his deposition, despite this theory appearing nowhere in his expert report. D.I. 148 at 8 (referring to this as "a strategic decision" by Alvogen). But Alvogen had no reason to ask Dr. Gudin about single-actor infringement because it was never disclosed in his expert reports. An expert's deposition is the time to probe the

opinions and evidence that were timely disclosed in the expert's report—not to blindly ask about undisclosed theories that might be sprung in summary judgment.

IV. The Prejudice to Alvogen Cannot Be Wholly Cured

In addition to arguing that Alvogen could have cured any prejudice by asking Dr. Gudin about his undisclosed theories, Pernix attempts to shrug off the real costs—both in time and money—associated with curing the prejudice caused by its late disclosure. Pernix does not address or attempt to distinguish this case from St. Clair, where Judge Stark excluded new infringement theories after finding, among other things, "that the Defendants will likely suffer prejudice if St. Clair is allowed to supplement its expert reports because Defendants will have to spend additional time and money to refute St. Clair's new theories." St. Clair Intellectual Prop. Consultants, Inc. v. Matsushita Elec. Indus. Co., C.A. No. 04-1436-LPS, 2012 U.S. Dist. LEXIS 40103, at *23 (D. Del. Mar. 26, 2012). Instead, it simply argues that "the cost of any such report would be the same regardless of when Pernix first argued single-actor infringement." D.I. 148 at 9. But the cost of preparing a new report is always greater than the cost of addressing all of the issues at once. And incurring those costs now—in the middle of trial preparation—is a significant tax on Alvogen's resources. Alvogen should not be forced to bear the costs of Pernix's last-minute addition of a new infringement theory.

Pernix also argues that any prejudice has already been cured because Alvogen was able to respond to Pernix's motion for summary judgment. But as discussed above, Pernix's late disclosure prevented Dr. Candiotti from providing his opinions on single-actor infringement. Thus, Alvogen's response does not rely on any expert opinions specifically directed to single-actor infringement. The fact that Alvogen was able to respond is irrelevant. If this were enough to avoid preclusion, parties could lie in wait and assert new theories on summary judgment with

no consequence—as long as the other side can muster an opposition, preclusion will never be warranted. This is not the law.[3]

V. Trial Will Inevitably Be Disrupted

Pernix claims that its late disclosure will not disrupt trial because the issue of whether the claims can be infringed by a single actor is purely legal. But Pernix cites no authority that this excuses a party from timely disclosing its infringement theories and allowing the other side to respond to them. And as discussed above, a single-actor theory presents unique factual issues that Alvogen's expert would likely have addressed in his report—for example, whether Alvogen's label encourages individual patients regarding each limitation of the claimed methods. Trial is now less than two months away, and Pernix makes no suggestion as to how the parties can maintain the existing pretrial schedule while giving Alvogen a fair opportunity to have its expert consider Pernix's single-actor infringement theory, provide an appropriate response, and modify the pretrial order to reflect Alvogen's positions on this issue.

VI. Bad Faith or Willfulness Are Not Required

Pernix argues that because Alvogen did not allege willfulness or bad faith, its motion must be denied. But Pernix does not address—let alone attempt to distinguish—the St. Clair case cited in Alvogen's motion, in which Judge Stark precluded a plaintiff from asserting untimely infringement theories despite specifically finding that there was no evidence of bad

[3] In the only case cited by Pernix, the court found that the plaintiffs failed to show "any actual harm or prejudice" because they failed to "cite to any particular discovery they were unable to complete." UCB, Inc. v. KV Pharm. Co., 692 F. Supp. 2d 419, 422 (D. Del. Mar. 9, 2010). This lack of prejudice was *confirmed* by the plaintiffs' "ability to respond to Defendant's Summary Judgment Motion on the issue[,]" but the ability to respond to a summary judgment motion does not, by itself, establish a lack of prejudice. Id.

faith or willfulness. 2012 U.S. Dist. LEXIS 40103, at *25-26. Evidence of bad faith or willfulness is one of many factors the Court should consider, but it is not a litmus test.

VII. Late-Disclosed Theories May Be Excluded, Even Important Ones

Pernix's hyperbole misses the point: every litigant considers all of its legal theories to be important, but that does not give a party carte blanche to raise new theories in addition to the ones it timely disclosed (i.e., the joint infringement theory on which Pernix has also moved for summary judgment). And as Alvogen pointed out in its motion, courts have excluded late-disclosed theories under similar circumstances—even "extremely important" ones. St. Clair, 2012 U.S. Dist. LEXIS 40103, at *21-23; AVM Techs., LLC v. Intel Corp., C.A. No. 10-610-RGA, 2013 U.S. Dist. LEXIS 66604, at *5 (D. Del. Mar. 29, 2013). Again, Pernix ignores these cases and makes no effort to distinguish them.

VIII. Conclusion

The length of Pernix's brief and the number of arguments raised should not distract from the simple fact that Pernix did not disclose the theory it now relies on in its motion for summary judgment—that the patient is a single-actor infringer—in its contentions or its expert reports, and it would be highly prejudicial to Alvogen if Pernix is allowed to assert a new infringement theory at this late stage of the case. Alvogen respectfully requests that the Court strike the single-actor infringement theory from Pernix's Opening Brief in Support of Its Motion for Summary Judgment (D.I. 120) and preclude it from pursuing this theory at trial.

Respectfully submitted,

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